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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,190	06/02/2005	Paolo Corvi Mora	27419-230	1281

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EXAMINER

KOSAR, AARON J

ART UNIT	PAPER NUMBER
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1651

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10/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,190	Applicant(s) CORVI MORA ET AL.	
	Examiner Aaron J. Kosar	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/4/2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 15-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/4/2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and argument filed June 4, 2007 in response to the non-final rejection, are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn. Upon further consideration, the indication of allowable subject matter in the Office action of February 1, 2007 is rescinded in favor of the arguments presented below.

Claims 1-11 and 15-22 are pending and have been examined on the merits.

For the reasons above, this Office action is **NON-FINAL**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 11, 15-18 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims read upon a composition comprising a powder formulation of a propolis active agent, a hydrophilic carrier, an amino acid, and a glycyrrhizate sweetening agent.

Claim 2 is indefinite because the phrase "corresponding composition..wherin the sole co-grinding auxiliary substance is an amino acid" is a relative term which renders the claim indefinite. The term "corresponding composition" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of "correspondence", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

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Claim 2 is also indefinite because the term "solubility" is a relative term defining a specific relation between a solute and solvent at a specific temperature. The term "solubility" in claim 2 is a relative term which renders the claim indefinite. The "solubility" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite solvent/temperature system by which solubility is measured, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus one would not be able to determine the metes and bounds of the claim rendering the claim indefinite.

Claims 3 and 11 are indefinite, because the phrase "and their derivatives" is unclear because the claims include elements not actually disclosed. The claims and specification do not provide the minimal structural components required to qualify or disqualify a compound as a derivative and do not provide the myriad of transformations encompassed by the term "and their derivatives". Thus the metes and bounds of the claims are unascertainable, rendering the claims indefinite. See MPEP § 2173.05(d).

Claims 15-18 and 20-21 recites the limitation "suitable excipients or diluents or combination thereof in product form". There is insufficient antecedent basis for these limitation in the claims, because the claims are dependent upon claim 1 directly or indirectly, and claim 1 recites a composition comprising a "powder formulation", but the terms "excipients" and "diluents" may reasonably be interpreted to include non-powder species, including water (see Examples 5, 6) and dimethicone emulsions (see Examples 6, 12) which would clearly create a composition which is not a powder.

Furthermore, claims 18, 20, and 21 recite the limitations of "lotions, creams, ointments, pastes, gels, and stick", "capsules, tablets" "solutions, and suspensions", and "spray" whereas,

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claim 1 recites a composition comprising a powder formulation; however, the aforementioned species in claims 18, 20, and 21 are clearly not powders or compositions comprising powders.

Thus, there is insufficient antecedent basis for these limitations in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 15-22 are rejected under 35 U.S.C. 103(a) as being obvious over AGA (A: PTO-892, 2/1/2007) in view of MANDAI (US 6,005,100 A) and ZAFFARONI (US 3,876,816 A) and KASORI (JP 60188036 A as evidenced by Derwent Abstract).

The general teachings of the claims are above.

AGA teaches a composition combining propolis; a hydrophilic carrier including a cyclodextrin; and a sweetening agent including maltose (column 12, lines 18-35, Example B-8). Aga also teaches a water-soluble, dry, powdery composition comprising: propolis; a hydrophilic carrier, including sodium citrate; an amino acid, including glycine; and, a sweetening agent,

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including trehalose (column 14 lines 27-4, Example B-15). Aga further teaches that propolis solutions may beneficially be dehydrated from liquid form, mixed with trehalose and cyclodextrin, and pulverized to produce a powdery extract. Additionally, Aga teaches that this propolis extract may beneficially be combined with one or more taste-/flavor-imparting agents and/or excipients; in combination with materials such as food products, cosmetics, colorant, health-food supplement, or anti-tumor (pharmaceutical) compositions; and, in various product forms, including the spectrum of solid, paste, and liquid forms (column 4).

MANDAI teaches that trehalose has sweetness, including the use of trehalose as a taste-improving agent or sweetener. Mandai also teaches that trehalose, maltose, glycine, and glycyrrhizin are useful for the same purpose as sweeteners (column 9, ¶ 6; column 10, ¶6-8 and portion spanning column 11).

ZAFFARONI teaches that glycyrrhizin is a sweetener (column 10, line 2).

KASORI teaches that the taste of glycyrrhizic acid-containing compositions are improved by adding organic salts, including citrate salts, and cyclodextrin. (Derwent Abstract).

To the extent that AGA is silent regarding the specific combination of the powder formulation of the specific combination of propolis-cyclodextrin-amino acid-glycyrrhizate, including wherein the amino acid is selected from glycine, glutamic acid, lysine, and serine, the claimed composition would have been obvious from the teachings of Aga.

From the composition taught by Aga (e.g. Example B-15), it would have been obvious to substitute trehalose with maltose, glycine, and/or glycyrrhizate since trehalose, maltose, glycine, and glycyrrhizin since the compounds are known and are taught by Mandai and Zaffaroni to be useful for the same purpose, as flavor-imparting/sweetening agents. Thus it would have been

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obvious to substitute one element (e.g. trehalose) for the other (maltose, glycine, and/or glycyrrhizin) to achieve the predictable result of a composition comprising a sweetening agent.

Furthermore, it would have been obvious to add cyclodextrin in the propolis-containing composition, because Aga teaches propolis-cyclodextrin containing compositions (Example B-8) and propolis-citrate-glycine compositions (Example B-15). In the latter instance, it would have been obvious to add cyclodextrin to the composition because Kasori beneficially teaches that the taste of glycyrrhizin-containing compositions is improved by the addition of cyclodextrin and citrate. Thus it would have been obvious to add cyclodextrin to the glycyrrhizin-containing composition for the beneficial and predictable result of enhancing the taste of said composition.

It would have been obvious to substitute glycine for another amino acid, because all amino acids share the same core $\text{H}_2\text{NCH(R)COOH}$ structure and are useful for the same purpose (as amino acids). Furthermore, there is nothing of record to preclude the use of any amino acid over any another amino acid and the claims merely require that the components be contacted, but does not indicate the criticality of identity of the amino acid selected. Absent evidence to the contrary and to the criticality of the amino acid employed, it would have been obvious to use any amino acid in the invention.

It would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable conditions (e.g. quantities and ratios of components), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by

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routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). See MPEP § 2145.05).

With regards to claim 2 reciting a summative or synergistic effects of the compounds to effect an enhanced solubility, it is noted that the features upon which applicant relies (i.e., a summative or synergistic effect which induces an enhanced solubility or the structure-functional origin thereof) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on a proposed unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed (e.g. in all instances where the composition is in powdered form and thus not dissolved in a solvent) would have been obvious to one of ordinary skill having the above cited references before him.

Though claims 5-18 and 20-21 are deficient as described in 35 USC 112 above, to the extent that the claims describe compositions in various product forms, it would be obvious to further modify the composition to said product forms, because Aga teaches that the composition

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may be “used alone or in combination with one or more other materials in compositions” and in a variety of physical forms and applications (e.g. see column 4, ¶4 through column 5, ¶4).

From the teachings of the references and the arguments, *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-11 and 15-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,6,9,10,11,15-17, 20-27, and 29 of copending Application No. 10515097.

Although the conflicting claims are not identical, they are not patentably distinct from each other; because, it would be obvious to provide an active substance (e.g. propolis and/or glycyrrhizin), cyclodextrin, and an amino acid, etc. and thus the broadest reasonable interpretation of the subject matter embraced by one invention in one application would overlap with the subject matter of the inventions embraced by the inventions of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ak/

Aaron Kosar

Examiner, Art Unit 1651

A handwritten signature in black ink, appearing to read 'Sandra E. Saucier', with a stylized flourish at the end.

**SANDRA E. SAUCIER
PRIMARY EXAMINER**